

IRB BRANCH REVIEW - TSS

Record Number(s)

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7/25/89 9/14/89
LN9/14/89 CUT

EFFICACY

FILE OR REG. NO. 56228-10

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 6/5/89, 7/24/89, 7/31/89

DATE OF SUBMISSION 5/24/89, 7/18/89, 7/21/89

DATE SUBMISSION ACCEPTED 7/25/89, 7/25/89, 9/14/89

TYPE PRODUCTS(S): I, D, H, F, N, R^x, S

DATA ACCESSION NO(S) none

PRODUCT MER. NO. 16

PRODUCT NAME(S) COMPOUND DRC-1339 CONCENTRATE

COMPANY NAME U. S. Department of Agriculture

MISSION PURPOSE label amendments, comments

CHEMICAL & FORMULATION 98% Starlicide concentrate

Efficacy Review: COMPOUND DRC-1339 CONCENTRATE, 56228-10
Animal Plant and Health Inspection Service (APHIS)
U. S. Department of Agriculture (USDA)
Hyattsville, MD 20782

200.0 INTRODUCTION

200.1 Uses

A 98.0% 3-Chloro-p-toluidine hydrochloride (Starlicide) concentrate labeled "FOR REFORMULATING PURPOSES ONLY" but bearing directions for mixing and applying baits to control starlings and unspecified types of blackbirds in hog feedlots, poultry feedlots, and cattle feedlots.

200.2 Background Information

See product jacket. The first application for registration for this product was submitted 9/14/64 by the U. S. Department of the Interior (USDI). Initial registration of this product, also by USDI, took place on 3/24/67. The original registration number was 6704-56. On 10/24/67, the product's formulation was changed from a 75% Starlicide (Compound DRC-1339) concentrate to a 98% Starlicide concentrate. The only Confidential Statement of Formula (CSF) now in the product jacket is dated 10/17/66 and is for a 75% a.i. concentrate.

In the submission discussed in the efficacy review of 12/31/88 (and EPA's letter of 4/25/89), APHIS had requested wholesale changes to the product use directions and had changed, without apparent request, the nominal claim of Starlicide content to 97.0%. Many of these changes addressed uses that have been accepted on "Special Local Needs" (under § 24[c] of FIFRA) labels issued by various states. As the proposed changes to the label would have expanded the use of this material greatly, I suggested that each change not now on a § 3 registered label be treated as a new use and be routed to HED and EFED for evaluations and determinations regarding needs for additional data to assess the "incremental risks" of the proposed new uses.

There are three current submissions.

1. A letter of 5/24/89 in which APHIS states
 - a. that a CSF submitted on 8/25/88 (not found in the product jacket) "was intended to replace the CSF . . . dated October 17, 1966, and identifies the registered source for this product that APHIS repackages";
 - b. that APHIS was not aware that many supporting safety and efficacy studies on Starlicide are not in EPA's files, that APHIS is searching its files to determine whether it has any appropriate studies on hand (including efficacy studies on the 24[c] uses developed for various states); and
 - c. that the product label was being revised to "reflect" EPA's various concerns, although APHIS claims that site restrictions for this type of product "would be difficult to accomplish within label

space availability and is not needed since the restrictions placed on this product will effectively limit its application to trained USDA personnel or personnel under their direct supervision".

2. A letter of 7/18/89 with which APHIS supplies
 - a. revised ("interim") labeling limited to the use patterns currently on the Federal label for 56228-10;
 - b. a revised CSF; and
 - c. a reiteration of APHIS's intent to supply existing data and/or to generate new data regarding the wildlife safety studies requested by EPA in conjunction with APHIS's application to expand the Federal label.
3. A letter of 7/21/89 to which is attached a copy of a settlement agreement between the U. S. Department of the Interior (USDI) and the Humane Society of the United States (HSUS) regarding the withdrawn 24(c) label for use of Starlicide egg baits in California to control ravens in areas of California where they prey upon desert tortoises. In addition to the egg baits, this use also covers the taking of ravens by other methods including shooting.

201.0 DATA SUMMARY

No efficacy data were submitted with these submissions.

Regarding the submission of 5/24/89, the only item that it is necessary to address concerns APHIS's arguments regarding specifying sites on the label. The argument that there is not enough room on the label is specious. For a highly restricted product such as this one, it is not unusual for registrants to develop extensive technical bulletins. In fact, APHIS has developed such a bulletin for the Livestock Protection Collar (56228-22). The notion that sites do not have to be spelled out on labels limited to use by certified APHIS employees or those under their direct supervision is equally ludicrous. While such individuals do bring a great deal of specialized training with them to jobs, it is imperative that restrictions and limitations on use of pesticides be defined in the labeling. EPA's entire approach to risk assessment is predicated upon definition and delineation of permissible (and nonpermissible) use sites. To permit a class of operators to use a bird toxicant for which use sites are described nebulously or not at all would be absurd and could invite misuses that could not be prosecuted effectively.

The revised label submitted on 7/18/89 is claimed to have incorporated EPA's comments in its letter of 4/5/89 which pertained to the claims that already were on the Federal label. Directions are presented only for feedlots for beef cattle, poultry, and swine. Directions permit applications to dry or frozen ground within beef cattle pens but prohibit such applications within pens containing poultry or swine. Permissible bait materials include poultry pellets and "grains such as rice, corn, or milo".

The revised CSF submitted 7/18/89 claims the product to be 98% 3-chloro-p-toluidine HCl. This concentration is also claimed on the revised label.

At the time that such information is provided, EPA will review whatever data relevant to this product that APHIS finds in its files and will comment upon those studies and the data gaps which APHIS believes remain to be filled.

The settlement agreement stipulates at which locations and under what conditions egg baits may be used in the future. Egg baits are to be permitted at several sites but are to be a back-up method to shooting except in two areas near high voltage transmission lines near Needles, CA. No more than 10 egg baits may be used at the Desert Tortoise Natural Area site, with no more than two eggs being permitted per platform. At the power line sites near Needles, at total of up to 32 poisoned eggs may be used, again with no more than two being used per platform. Baits are to be kept under constant surveillance when deployed in the field. HSUS is to be informed of all egg bait applications before they are made. No ravens may be killed at the Twentynine Palms Marine Corps Landfill, a site where USDI had judged the raven control program to have been 2/3 completed in 1989.

202.0 CONCLUSIONS

In reference to comments in your letter of May 24, 1989, you should note that it is imperative that sites be defined for all use patterns, regardless of the class of users to which a product is restricted. Defining sites is critical to the Agency's assessments of environmental and human hazards associated with the use of particular pesticide chemicals or products. If space on the container label is limited, you should consider the "Technical Bulletin" approach when developing use directions for your intended expanded labeling for the DRC-1339 Concentrate product.

The "DIRECTIONS FOR USE" on your proposed revised label are adequate. However, the following changes are needed:

1. from the third sentence in first paragraph of "FORMULATION DIRECTIONS", place a comma after "pellets" and delete "or grains such as";
2. change the fourth (and last) sentence of the first paragraph of "FORMULATION DIRECTIONS" to read

"Do not use bait materials that have less than 2500 particles/lb or more than 25,000 particles/lb.";

and

3. in second sentence of second paragraph of "FORMULATION DIRECTIONS", change "will" to "should" (in both instances of its use).

William W. Jacobs
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Insecticide-Rodenticide Branch
September 14, 1989